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Guidelines on Voluntary Labeling of Biotech Foods 2006

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Report Highlights:
The Hong Kong government recently released guidelines on voluntary labeling of biotech foods. The guidelines are voluntary in nature and apply to prepackaged foods only. This report lists the full guidelines. In order to better explain the guidelines, the Hong Kong government has prepared a set of "frequently asked questions on the guidelines". The questions and respective answers are also included in this report.

Includes PSD Changes: No
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Background

The Hong Kong government recently released guidelines on voluntary labeling of biotech foods. The guidelines are voluntary in nature and apply to prepackaged foods only. Currently, the Hong Kong government has no specific legislative regulations with regard to the labeling of biotech food products. The Hong Kong government makes no distinction between conventional and biotech foods. All are subject to the same food safety regulation. Despite the incessant requests for mandatory labeling for biotech foods by certain sectors in the community such as green groups and consumer groups, the Hong Kong government has not introduced mandatory labeling at this stage on the grounds that there is no consensus on this subject in international arena such as Codex.

In a proposal submitted to the Hong Kong Legislative Council in 2003, the Hong Kong government announced its intention to launch a program of voluntary labeling for pre-packaged food and mandatory pre-market safety assessment requirements for all food products. While the Hong Kong government has not set a date for the implementation of the mandatory pre-market safety assessment, it has recently released the guidelines for voluntary labeling of biotech foods in order to answer the public's call for consumers' right to make an informed choice of biotech foods.

A Summary of the Guidelines

The guidelines were formulated by a working group established under the Center for Food Safety, with members coming from various sectors including manufacturing, wholesale, retail, consumer groups and government departments. The guidelines are advisory in nature and do not have any legal effect. Adoption is entirely voluntary and is not binding. The guidelines apply to prepackaged food.

The guidelines are based on the following four principals.

- The labeling of biotech food will comply with the existing food legislation.
- The threshold level applied in the guidelines for labeling purpose is 5 percent, in respect of individual food ingredient.
- Additional declaration on the food label is recommended when significant modifications of the food, e.g. composition, nutrition value, level of anti-nutritional factors, natural toxicant, presence of allergen, intended use, introduction of an animal gene, etc, have taken place.
- Negative labeling is not recommended.

As the guidelines are voluntary, U.S. food exports should not be affected if they choose not to have any biotech labeling. However, it should be noted that the Hong Kong government does not encourage negative labeling when no biotech counterparts of the respective products ever exist. Also, the Hong Kong government does not encourage negative labeling using very definite terms such as:

- GMO free,
- Free from GM ingredients, etc

For products with such definite negative labeling, the government may take the initiative to test the products against GM ingredients and a zero tolerance will be adopted for testing purposes. If products are found to have misleading labeling, a retailer may be subject to

prosecution under Section 61 – False Labeling and Advertisement of Food or Drugs of Chapter 132 Public Health and Municipal Services Ordinance. (Available at http://www.legislation.gov.hk/eng/home.htm)

If the trade chooses to apply negative labeling, the government advises to use less definite terms such as “sourced from non-GM sources” (which contains less than 5 percent of GM content) and to have documentation to substantiate such declaration.

The guidelines are provided in appendix I. In order to better explain the guidelines, the Hong Kong government has prepared a set of "frequently asked questions on the guidelines", which is included in appendix II.

Appendix I

GUIDELINES ON VOLUNTARY LABELLING OF GENETICALLY MODIFIED (GM) FOOD

PURPOSE

The Guidelines on Voluntary Labelling of GM Food (the Guidelines) set out the principles underlying the recommended labelling approaches for GM food, and provide reference for the trade to make truthful and informative labels in a consumer-friendly manner.

BACKGROUND

2. The international community is working towards a consensual system on GM food labelling. However, there is no consensus on GM food labelling in the Codex Alimentarius Commission (Codex) and it is unlikely that internationally agreed standards can be established in the near future. Nevertheless, a number of countries have introduced their own labelling requirements on GM food. In order to enhance consumers' knowledge and right to make an informed choice on GM food, the Centre for Food Safety (CFS) supports the local food trade's initiative in setting up a voluntary labelling system for GM food. A Working Group comprising representatives from the food trade, the Consumer Council and the relevant Government departments was set up by the Food and Environmental Hygiene Department (subsequently taken up by the Centre for Food Safety (CFS)) to formulate the Guidelines.

3. The Guidelines are advisory in nature and members of the trade are encouraged to adopt the Guidelines which have been jointly developed by representatives of the trade, consumer bodies and government departments. Members of the trade are reminded that they should not falsely describe their food products, which section 61 of the Public Health and Municipal Services Ordinance (Cap 132) will apply. [http://www.legislation.gov.hk/eng/home.htm] The guidelines will be updated as and when necessary to reflect changes in technology and the international developments of GM food labelling requirement.

BASIC PRINCIPLES

4. The Guidelines embody the following basic principles:

5. **Principle 1:** The Public Health and Municipal Services Ordinance (Cap. 132) provides the legislative framework for food safety control in Hong Kong. As stipulated in section 61, no person shall give any food sold by him or display with any food exposed for sale by him, a label, which falsely describes the food. In addition, the Food and Drugs (Composition and Labelling) Regulations require that any prepackaged food shall be marked and labelled in the prescribed manner.

6. **Principle 2:** The threshold level currently applied in the Guidelines for labelling purpose is 5%, in respect of individual food ingredient, taking account of adventitious mixing of GM and non-GM crops during harvest, transportation, processing and storage. This threshold level reflects a more pragmatic and realistic level that the trade can achieve at this stage.

7. **Principle 3:** Additional declaration on the food label is recommended when significant modifications have taken place under the following conditions –

(a) the composition or nutritional value is significantly different from that of its conventional counterpart;

(b) the level of anti-nutritional factors or natural toxicants is significantly different from that in its conventional counterpart;

(c) the presence of an allergen that is not found in its conventional counterpart;

(d) the intended use of the food is significantly different from that of its conventional counterpart; or

(e) an animal gene has been introduced into food of plant origin.

8. **Principle 4:** Negative labelling is not recommended for food without GM counterparts, as it would be misleading to consumers.

SCOPE

9. The Guidelines are applicable to prepackaged food that contains food or food ingredients that are known to have a GM counterpart.[1]

DETAILED GUIDELINES

Interpretation

10. The following definitions are applicable to the Guidelines.

"genetically modified (GM) food"(??????) refers to any food or food ingredient that is, or is derived from, an organism in which the genetic material has been modified using modern biotechnology;

"GM free"(????????) refers to any food ingredients absolutely free (i.e. zero) of GM materials;

"genetically modified organism (GMO)" (??????) means any organism in which the genetic material has been modified using modern biotechnology;

"ingredient"(??) means any substance, including any additive and any constituent of a compound ingredient, which is used in the manufacture or preparation of a food and which is still present in the finished product, even if in altered form;

"labelling" (????????) , in relation to a food, includes any words, particulars, trade mark, brand name, pictorial matter or symbol relating to the food and appearing on the packaging of the food or on any document, notice, label, ring or collar accompanying the food;

"modern biotechnology" (??????) refers to the application of the following techniques that overcome natural physiological reproductive or

recombination barriers and that are not used in traditional breeding and selection:

(i) *in vitro* nucleic acid techniques, including but not limited to recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(ii) fusion of cells beyond the taxonomic family;

"prepackaged food"(??????) means any food packaged, whether completely or partially, in such a way that –

(a) the contents cannot be altered without opening or changing the packaging; and

(b) the food is ready for presentation to the ultimate consumer or a catering establishment as a single food item.

Positive Labelling

11. Any food items[2] with 5% or more GM materials in their respective food ingredient(s) should be labelled as "genetically modified" in parenthesis following the name of the food/food ingredient in the list of ingredients. Alternatively, the words "genetically modified" may appear in a prominently display footnote to the list of ingredients, whereas the ingredient concerned would be marked with an asterisk "*". However, the font size of the footnote should be at least the same size as the list of ingredients. Examples are,

For whole food or food with single ingredient [3]:

List of Ingredients: soya beans (genetically modified)
???:??(????)

For processed food:

List of Ingredients: flour, soya flour (genetically modified), water, sugar, butter, and walnut
???:??,???(????),?,?,??,??

or
List of Ingredients: flour, soya flour*, water, sugar, butter, and walnut
*genetically modified
???:??,???*,?,?,??,??
*????

Note:
If both the English and Chinese Languages are used in the labelling of prepackaged food, the name of the food and the list of ingredients shall appear in both languages.

12. For any GM food with significant modifications that have taken place under the following conditions –

(a) the composition or nutritional value is significantly different from that of its conventional counterpart;

(b) the level of anti-nutritional factors or natural toxicants is significantly different from that in its conventional counterpart;

(c) the presence of an allergen that is not found in its conventional counterpart;

(d) the intended use of the food is significantly different from that of its conventional counterpart; or

(e) an animal gene has been introduced into food of plant origin,

the label should provide additional words in conjunction with the name of the food or food ingredients to inform consumers the changed characteristics. For example, product containing soya bean that is genetically modified to contain high oleic acid as an ingredient, the ingredient should be labelled as "soya bean (genetically modified to contain high oleic acid)".

13. If any GM food and their products of plant origin contain animal gene, additional information regarding the origin of animal gene[4] following the name of food ingredient is recommended. For example, a GM food "xx" with gene from animal "A" can be labelled as:

List of Ingredients: water, sugar, xx (genetically modified, contains gene(s) from A)
???:?,?, **xx (**????,????**A**???**)**

Negative Labelling

14. "GM free" and similar labels (e.g. GMO free, free from GM ingredients, etc.) will give consumers the impression that the food products so labelled are totally free of GM content. Since there is the possibility of unintentional mixing of GM and non-GM crops, a truly "GM free" status is very difficult to attain. Such absolute terms may therefore be misleading to consumers and are not recommended to be used.

15. Should the trade wish to apply negative labelling other than "GM free" and similar labels to any food ingredients derived from non-GM sources (which contains less than 5% of GM content), the trade should ensure that there should be documentation to substantiate such declaration. The trade is also reminded to comply with the provisions laid down in Section 61 of the Public Health and Municipal Services Ordinance (Cap 132).

16. In addition, any such negative labelling is not recommended to indicate or imply that a certain food, as a whole, is from non-GM sources, unless all of the concerned ingredients in the product are derived from non-GM sources and have fulfilled the requirement stated in para. 15.

EFFECTIVE DATE

17. The Guidelines will come into operation on 28 July 2006.

Centre for Food Safety
Food and Environmental Hygiene Department
28 July 2006

[1] Negative labelling is not recommended for food of which no GM varieties have been produced, as it would be misleading to consumers.

[2] Paragraph 11 does not apply to food products, which do not contain detectable DNA or protein, including highly refined food (such as sugar and oil) and highly processed food, unless the food products have significant modification that have taken place under the conditions as stated in paragraph 12.

[3] Schedule 4 of the Food and Drugs (Composition and Labelling) Regulations exempts any food consisting of a single ingredient to comply with the labelling requirements imposed under paragraph 2 of Schedule 3 to the Regulations. However, paragraph 3 of Schedule 3 provides that if any prepackaged food which is exempted from paragraph 2 of Schedule 3 is marked or labelled with a list of ingredients on its own initiative (regardless whether the ingredients include the GM food), such list of labelling shall comply with the labelling requirements imposed under Schedule 3.

[4] No GM crops available in the international market at present contain any animal genes.

Appendix II

Frequently Asked Questions on the Guidelines on Voluntary Labelling of Genetically Modified (GM) Food (for Trade)

Q. 1 What is the purpose of developing these guidelines?

A. 1 In order to enhance consumers' knowledge and right to make an informed choice on GM food, the Centre for Food Safety (CFS) supports the local food trade's initiative in setting up a voluntary labelling system for GM food. The Guidelines serve as a reference to facilitate the trade to make truthful claims of GM foods.

Q. 2 Why does the Government propose to introduce the voluntary labelling guidelines on GM food, instead of a mandatory labelling scheme?

A. 2 When deciding the regulatory framework on GM food labelling, a number of factors, including trade impact and public concern, have to be taken into account.

In the past public consultation exercise, the majority of views collected are in support of mandatory labelling, and the presence of GM content in any ingredient of a food product above a threshold level should be labelled. However, as there was concern about the possible price rise after the introduction of a mandatory labelling system, a regulatory impact assessment (RIA) on the labelling of GM food in Hong Kong was conducted and revealed that there would be additional cost to the trade, in particular the small and medium sized companies, if a mandatory scheme was to be implemented. Moreover, there is at present no international consensus on the labelling of GM food. The Government will need to engage the trade and other stakeholders and consult them before coming to any conclusion on whether there should be mandatory labelling requirement for GM food. In response to consumers' increasing demand for more product information, the Government considers it a pragmatic move to introduce a voluntary labelling scheme for GM food at this stage.

Q. 3 What are the current international practices on labelling of GM food?

A. 3 The international community is working towards a consensual policy on GM food labelling. However, the Codex Alimentarius Commission of the United Nations is unlikely to be able to set internationally agreed standards in the near future. At present, the regulatory approach on GM food labelling varies in different countries and areas, and can be broadly classified as voluntary or mandatory. For the voluntary labelling approach, only GM food that is significantly different from its conventional counterpart, in terms of composition, nutritional value and allergenicity, needs to be labelled. The U.S. and Canada are examples of countries adopting this approach. For the mandatory approach, it can be further classified as two categories, i.e. “pan-labelling” or “labelling for designated products only”. The “pan-labelling” category requires that any food products containing GM materials exceeding a threshold level or food with any significantly different characteristics as a result of genetic modification must be labelled. The EU, Australia and New Zealand are examples of countries adopting this approach. The “labelling for designated products only” category requires that only the designated products which are genetically modified need to be labelled. Countries and areas like Japan, Korea, Taiwan and Mainland China are adopting this approach.

Q. 4 How were the guidelines developed?

A. 4 A Working Group comprising representatives from the food trade, Consumer Council and relevant Government departments was set up by the Food and Environmental Hygiene Department to formulate the Guidelines. After the Centre for Food Safety was established, the Working Group met and finalised the draft Guidelines.

Q. 5 Are these guidelines legal binding?

A. 5 The Guidelines are advisory in nature and have no legal effect. Adoption is entirely voluntary and is not binding. Nevertheless, members of the trade are encouraged to adopt the Guidelines to standardise consumers' information.

Q. 6 Are these guidelines applicable to all types of food including loose food items sold in Hong Kong?

A. 6 These guidelines are only applicable to pre-packaged food sold in Hong Kong and are voluntary in nature.

Q. 7 What kind of food products should be labelled under the Guidelines?

A. 7 Any food items with 5% or more GM materials in their respective food ingredient(s) could be labelled as “genetically modified” in a prescribed manner. Additional declaration on the food label is recommended when significant modifications that have taken place under the following conditions: (a) the composition or nutritional value is significantly different from that of its conventional counterpart; (b) the level of anti-nutritional factors or natural toxicants is significantly different from that in its conventional counterpart; (c) the presence of an allergen that is not found in its conventional counterpart; (d) the intended use of the food is significantly different from that of its conventional counterpart; or (e) an animal gene has been introduced into food of plant origin.

Q. 8 Why is a threshold level of 5% adopted in the Guidelines?

A. 8 In the Guidelines, a threshold level of 5% is adopted in order to address the problem of unintentional adventitious mixing between GM and non-GM food materials during harvest, storage and transportation. This chosen level reflects what the trade can deliver at this stage. Furthermore, the analysis in the Regulatory Impact Assessment on Labelling of GM Food suggested that the cost to the trade could increase significantly if the threshold level becomes more stringent. This threshold level was also adopted by overseas countries or areas including Canada, Japan and Taiwan.

Q. 9 What are the pros and cons of adopting a threshold level of 5% or 1%?

A. 9 Adopting a threshold level of 5%:

Pros

- At present, there is no international consensus on threshold level for GM food labelling and the adopted threshold levels vary from country to country with levels ranged from 0.9 to 5%. Hence, a threshold level of 5% would impose less technical difficulties on the trade.
- This approach will incur less additional cost on the food production.
- This approach will currently be more practical or achievable among the local food trade.

Cons

- This approach will not fully address the need of consumers who would like to know the presence of a lower content of GM materials, so as to make informed choices.

Adopting a threshold level of 1%:
Pros

- This approach will address better the need of consumers who would like to know whether food contains any GM materials at all, so as to make informed choices.

Cons

- This approach will currently be less practical or achievable among the local food trade.
- This approach will limit consumer choice to those foods that have been grown intentionally to meet the non-GM market due to the problem of unintentional adventitious mixing between GM and non-GM food materials in the production of field crops.

Q. 10 Do the Guidelines cover the aspect of negative labelling? What is the approach proposed in these guidelines?

A. 10 To be consistent with the international approach, negative labelling is not recommended for food of which no GM varieties have been produced as it would be

misleading to consumers. The trade could browse the webpage of the "GM Food Database" in our website to know more about which foods have GM counterparts. Furthermore, absolute terms such as "GM free" and similar labels (e.g. GMO free, free from GM ingredients, etc.) are not recommended to be used, as such absolute terms may be misleading to consumers. Since there is the possibility of unintentional mixing of GM and non-GM crops, a truly "GM free" status is very difficult to attain.

If the trade would like to use labelling besides the aforesaid absolute terms to describe their products as being made from non-GM source, they need to have documentation to substantiate such declaration. Moreover, if a product contains multiple ingredients, such declaration can only be used when ALL of the ingredients in the product are derived from non-GM sources and documentation are available to substantiate the claim.

Q. 11 Will the Guidelines be reviewed in the future?

A. 11 Subject to further development, in areas like technological advancement, international consensus on the labelling approach, etc., these guidelines may be reviewed and updated.

Q. 12 Do the Guidelines require additional declaration if the GM food contains an allergen?

A. 12 Food allergy is common and a range of food products such as peanuts and eggs, no matter if they are GM or not, may contain allergenic proteins which can cause allergic reaction. Under the current legislation, if a food consists of or contains any of (i) cereals containing gluten; (ii) crustacea and its products; (iii) eggs and its products; (iv) fish and its products; (v) peanuts, soyabeans and their products; (vi) milk and its products and (vii) tree nuts and nut products, the name of the substance shall be specified in the list of ingredients. In addition, the voluntary Guidelines on GM food labeling also suggest those GM foods with the presence of an allergen, which is not found in its conventional counterpart to have additional declaration on the food label.

Q. 13 How should the trade label food with single ingredient which is genetically modified?

A. 13 Schedule 4 of the Food and Drugs (Composition and Labelling) Regulations exempts any food consisting of a single ingredient to comply with the labelling requirements imposed under paragraph 2 of Schedule 3 to the Regulations. However, paragraph 3 of Schedule 3 provides that if any prepackaged food which is exempted from paragraph 2 of Schedule 3 is marked or labelled with a list of ingredients on its own initiative (regardless whether the ingredients are GM or not), such list of labelling shall comply with the labelling requirements imposed under Schedule 3.

Therefore, if traders adopt this voluntary guidelines on GM food labeling, food with single ingredient consisting of 5% or more GM materials is to be labelled as "genetically modified" in parenthesis following the name of the food in the list of ingredients or in a prominently displayed footnote to the list of ingredients. Such labelling should conform in all respects with the requirements of the marking and

labelling of prepackaged foods in the said Schedule 3.

Q.14 What are the anti-nutritional factors mentioned in the Guidelines?

A.14 Anti-nutritional factors are those compounds that inhibit the normal uptake or utilization of nutrients. The trypsin inhibitor commonly found in soya bean is one of the examples of anti-nutritional factors. Trypsin inhibitor can inhibit the activities of some digestive enzymes and may affect the process of nutrient absorption from the overall diet.

Q. 15 How can the trade get information about those GM food products that have been approved so far?

A. 15 If the trade would like to obtain a list of GM food products which were approved to be sold in the market, they may visit the "GM Food Database" in our website. The database has included the list of GM food products that have been gone through the safety assessment processes and have been approved in some countries such as the United States, Canada, Australia and New Zealand.

Centre for Food Safety
Food and Environmental Hygiene Department
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